

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: : 10/646,970
Applicant : Carol J. Phelps
Conf. No.: : 3048
Filed : August 21, 2003
TC/A.U. : 1600/1632
Examiner : Joseph T. Woitach
Title : Porcine Animals Lacking Any Expression Of Functional Alph 1,3
Galactosyltransferase

Docket No.: : 10758.105009 REV1004
Customer No. : 20786

Mail Stop AMENDMENT
Commissioner for Patents
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Sir:

Applicant cites the information on the attached Form PTO/SB/08A, "Information Disclosure Statement by Applicant," pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98. Applicant has enclosed a copy of each cited foreign patent document and non-patent literature.

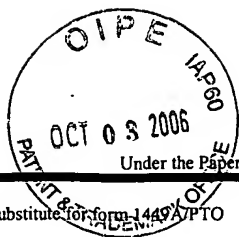
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Respectfully submitted,


Rebecca J. Kaufman
Reg. No. 44,819

Date: September 25, 2006

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1180 Peachtree Street, N.E.
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Substitute for form 1449 of PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet **1** of **10****Complete if Known**

Application Number	10/646,970
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First Named Inventor	Carol J. Phelps
Group Art Unit	1632
Examiner Name	Joseph T. Woitach
Attorney Docket Number	10758.105009 REV 1004

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U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code (if known)			
	AA	4,797,368	A	Carter <i>et al.</i>	01-10-1989	
	AB	4,863,852	A	Wilkins <i>et al.</i>	09-05-1989	
	AC	5,175,383	A	Leder <i>et al.</i>	12-29-1992	
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	AO	6,235,969	B1	Stice <i>et al.</i>	05-22-2001	
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		Office ³	Number	Kind Code ² (if known)				
	AAA	EP	0669829	B1	Biotransplant, Inc.	08-08-2001		
	AAB	JP	1994-253856	A1	MASAYA <i>et al.</i> ,	09-13-1994	Seq ID No.1 Alignment	
	AAC	WO	94/02616	A1	Regents of Univ. of Michigan	02-03-1994		

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				Group Art Unit	1632
Examiner Name	Joseph T. Weitach				
Attorney Docket Number	10758.105009 REV 1004				
Sheet	2	of	10		

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		Office ³	Number	Kind Code ² (if known)				
	BA	WO	94/09803	A1	Biotransplant Inc.	05-11-1994		
	BB	WO	94/21799	A1	Austin Research Inst.	09-29-1994		
	BC	WO	94/24870	A1	Biotransplant, Inc.	11-10-1994		
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	BF	WO	95/34202	A1	Alexion Pharmaceuticals Inc.; Austin Research Institute	12-21-1995		
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	BT	WO	99/21415	A1	Biotransplant Inc.	05-06-1999		
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	BAB	WO	03/055302	A1	University of Missouri	07-10-2003		
	BAC	WO	04/016742	A2	Immerge Biotherapeutics Inc.	02-26-2004		

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Sheet	3	of	10		

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	CA	AYARES, D., <i>et al.</i> , (PPL Therapeutics, Inc.), "Gene targeting in livestock," Transgenic Animal Research Conference (hosted by Univ. of Calif. at Davis biotechnology program, at the Granlibakken Conf. Ctr. in Tahoe City, CA, July 1999 [http://www.biotech.ucdavis.edu]), abstract at p. 20.	
	CB	AYARES, D., <i>et al.</i> , (PPL Therapeutics, Inc.), "Gene targeting in livestock for production of novel biopharmaceuticals," <i>ISB News Report</i> (published by Information Systems for Biotechnology), Nov. 1999:5-6, at http://www.isb.vt.edu/news/1999/Nov44.pdf	
	CC	AYARES, D., <i>et al.</i> , "Cloning pigs deficient in α 1,3 galactosyltransferase," <i>Graft</i> , 4(1):80-83 (2001).	
	CD	BACH, F.H., <i>et al.</i> , "Delayed xenograft rejection," <i>Immunol. Today</i> , 17(8):379-384 (August 1996).	
	CE	BETTHAUSER, J., <i>et al.</i> , "Production of cloned pigs from in vitro systems," <i>Nature Biotechnology</i> , 18(10):1055-1059 (October 2000).	
	CF	BONDIOLI, K., <i>et al.</i> , "Cloned pigs generated from cultured skin fibroblasts derived from a H-transferase transgenic boar," <i>Molecular Reproduction and Development</i> , 60(2):189-195 (October 2001).	
	CG	BRANDON, E.P., <i>et al.</i> , "targeting the mouse genome: A compendium of knockouts (part I)," <i>Current Biology</i> , 5[6]:625-634 (1995).	
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	CJ	BUTLER, D., "Xenotransplant experts express caution over knockout piglets," <i>Nature</i> , 415(6868):103-104 (January 10, 2002).	
	CK	CAPECCHI, M.R., <i>et al.</i> , "Altering the genome by homologous recombination," <i>Science</i> , 244(4910):1288-1292 (June 16, 1989).	
	CL	CLARK, A.J., <i>et al.</i> , "Gene targeting in livestock: a preview," <i>Transgenic Res.</i> , 9(4-5):263-275 (2000).	
	CM	CLARK, G.F., <i>et al.</i> , "Toxin A from <i>Clostridium difficile</i> binds to rabbit erythrocyte glycolipids with terminal Gal alpha 1-3Gal beta 1-4GlcNAc sequences," <i>Arch.Biochem.Biophys.</i> , 257(1):217-229, (Aug. 15, 1987).	
	CN	COOPER, D.K., <i>et al.</i> , "Oligosaccharides and discordant xenotransplantation," <i>Immunol. Rev.</i> , 141:31-58 (October 1994).	
	CO	COOPER, D.K.C., <i>et al.</i> , "Genetically engineered pigs," <i>Lancet</i> , 342:682-683 (Sept. 11, 1993).	
	CP	COSTA, C., <i>et al.</i> , "Expression of the human α 1,2-fucosyltransferase in transgenic pigs modifies the cell surface carbohydrate phenotype and confers resistance to human serum-mediated cytolysis," <i>FASEB J.</i> , 13:1762-1773 (Oct. 1999).	

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	DA	DABKOWSKI, P.L., <i>et al.</i> , "Characterisation of a cDNA clone encoding the pig alpha 1,3 galactosyltransferase: implications for xenotransplantation," <i>Transplant Proc.</i> , 25(5):2921 (October 1993).	
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	DC	DAI, Y., <i>et al.</i> , "Targeted disruption of the α 1,3-galactosyltransferase gene in cloned pigs," <i>Nature Biotechnology</i> , 20:251-255 (March 2002).	
	DD	DALMASSO, A.P., <i>et al.</i> , "Inhibition of complement-mediated endothelial cell cytotoxicity by decay-accelerating factor: Potential for prevention of xenograft hyperacute rejection," <i>Transplantation</i> , 52(3):530-533 (Sept. 1991).	
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	DF	D'APICE, A.J., <i>et al.</i> , "Two genetic approaches to the galactose alpha 1,3 galactose xenoantigen," <i>Transplant Proc.</i> , 28(2):540 (April 1996).	
	DG	DENNING, C., <i>et al.</i> , "Gene targeting in primary fetal fibroblasts from sheep and pig," <i>Cloning Stem Cells</i> , 3(4):221-231 (2001).	
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	DO	GASSMANN, M., <i>et al.</i> , "Maintenance of an extrachromosomal plasmid vector in mouse embryonic stem cells," <i>Proc. Natl. Acad. Sci. USA</i> , 92(5):1292-1296 (February 28 1995).	
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	EA	HAMMER, R.E., <i>et al.</i> , "Production of transgenic rabbits, sheep and pigs by microinjection," <i>Nature</i> , 315(6021):680-683 (June 20-26, 1985).	
	EB	HANCOCK, W., "Hyde Park Speakers Corner: Xeno-stagnation," <i>AST Newsletter</i> , 6(3):31-33 (Summer 1999) (American Society of Transplantation, Moorestown, NJ) (also published at http://www.a-s-t.org/library/newsArchive/vol6-3/hydepark.htm).	
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	EE	HASTY, P., <i>et al.</i> , "The length of homology required for gene targeting in embryonic stem cells," <i>Mol. Cell Biol.</i> , 11(11):5586-5591 (November 1991).	
	EF	HAYASHI, S., <i>et al.</i> , "Adenovirus-mediated gene transfer of antisense ribozyme for alpha (1,3)galactosyltransferase gene and alpha (1,2)fucosyltransferase gene in xenotransplantation," <i>Transplant Proc.</i> , 29(4):2213 (June 1997).	
	EG	HENNET, T., "The galactosyltransferase family," <i>Cell. Mol. Life Sci.</i> , 59:1081-1095 (2002).	
	EH	JOYNER, A.L., "Production of a mutation in mouse En-2 gene by homologous recombination in embryonic stem cells," <i>Nature</i> , 338(6211):153-156 (March 9, 1989).	
	EI	JOZIASSE, D.H., <i>et al.</i> , "Bovine $\alpha 1 \rightarrow 3$ -galactosyltransferase: Isolation and characterization of a cDNA clone: Identification of homologous sequences in human genomic DNA," <i>J. Biol. Chem.</i> , 264(24):14290-14297 (Aug. 25, 1989).	
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	EK	JOZIASSE, D.H., <i>et al.</i> , "Murine $\alpha 1 \rightarrow 3$ -galactosyltransferase: A single gene locus specifies four isoforms of the enzyme by alternative splicing," <i>J. Biol. Chem.</i> , 267(8) 5534-5541 (March 15, 1992).	
	EL	JOZIASSE, D.H., <i>et al.</i> , "Xenotransplantation: the importance of the Gal $\alpha 1,3$ Gal epitope in hyperacute vascular rejection," <i>Biochim. Biophys. Acta</i> , 1455(2-3):403-418 (October 8, 1999).	
	EM	JUST, I., <i>et al.</i> , "The low molecular mass GTP-binding protein rho is affected by toxin A from <i>Clostridium difficile</i> ," <i>J. Clin. Invest.</i> , 95:1026-1031 (1995).	
	EN	KATAYAMA, A., <i>et al.</i> , "Porcine α -1,3-galactosyltransferase: full length cDNA cloning, genomic organization, and analysis of splicing variants," <i>Glycoconjugate Journal</i> , 15:583-589 (1998).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/646,970
				Filing Date	August 21, 2003
				First Named Inventor	Carol J. Phelps
				Group Art Unit	1632
				Examiner Name	Joseph T. Weitach
(use as many sheets as necessary)				Attorney Docket Number	10758.105009 REV 1004
Sheet	6	of	10		

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	FA	KELLY, R.J., <i>et al.</i> , "Sequence and expression of a candidate for the human Secretor blood group alpha (1,2)fucosyltransferase gene (FUT2). Homozygosity for an enzyme-inactivating nonsense mutation commonly correlates with the non-secretor phenotype," <i>J. Biol. Chem.</i> , 270(9):4640-4649 (Mar. 3, 1995).	
	FB	KILBY, N.J., <i>et al.</i> , "Site-specific recombinases: tools for genome engineering," <i>Trends in Genetics</i> , 9(12):413-421 (December 1993)..	
	FC	KOIKE, C., <i>et al.</i> , "Comparison of the regulatory regions of the of α 1,3galactosyltransferase gene between murine and porcine species," <i>Transplantation Proceedings</i> , 33:710-711 (2001).	
	FD	KOIKE, C., <i>et al.</i> , "Direct gene replacement of the mouse α (1,3)-galactosyltransferase gene with human α (1,2)-fucosyltransferase gene: Converting α -galactosyl epitopes into H antigens," <i>Xenotransplantation</i> , 4:147-153 (1997).	
	FE	KOIKE, C., <i>et al.</i> , "Introduction of α (1,2)-fucosyltransferase and its effect on α -Gal epitopes in transgenic pig," <i>Xenotransplantation</i> , 3:81-86 (1996).	
	FF	KOIKE, C., <i>et al.</i> , "Isolation of the regulatory regions and genomic organization of the porcine α 1,3-galactosyltransferase gene," <i>Transplantation</i> , 70(9):1275-1283 (Nov. 15, 2000).	
	FG	KOIKE, C., <i>et al.</i> , "Molecular basis of evolutionary loss of the α 1,3-galactosyltransferase gene in higher primates," <i>J. Biol. Chem.</i> , 277(12):10114-101120 (March 22, 2002).	
	FH	LAI, L., <i>et al.</i> , "Production of α -1,3-galactosyltransferase knockout pigs by nuclear transfer cloning," <i>Science</i> 295:1089-1092 (February 8, 2002) and supplementary data, <i>Science Express</i> , January 3, 2002.	
	FI	LARSEN, R.D., <i>et al.</i> , "Frameshift and nonsense mutations in a human genomic sequence homologous to a murine UDP-Gal:beta-D-Gal(1,4)-D-GlcNAc α (1,3)-galactosyltransferase cDNA," <i>J. Biol. Chem.</i> , 265(12):7055-7061 (April 25, 1990).	
	FJ	LARSEN, R.D., <i>et al.</i> , "Isolation of a cDNA encoding a murine UDPgalactose:beta-D-galactosyl- 1,4-N-acetyl-D-glucosaminide α -1,3-galactosyltransferase: expression cloning by gene transfer," <i>Proc. Natl. Acad. Sci., U S A.</i> , 86(21):8227-8231 (November 1989).	
	FK	LARSEN, R.D., <i>et al.</i> , "Molecular cloning, sequence, and expression of a human GDP-L-fucose:beta-D-galactoside 2- α -L-fucosyltransferase cDNA that can form the H blood group antigen," <i>Proc. Natl. Acad. Sci., U S A.</i> , 87(17):6674-6678 (September 1990).	
	FL	LO, N.W., <i>et al.</i> , "Transcription of the beta-galactoside α 2,6-sialyltransferase gene in B lymphocytes is directed by a separate and distinct promoter," <i>Glycobiology</i> , 6(3):271-279 (April 1996).	
	FM	LUCKOW, V.A., <i>et al.</i> , "Trends in the development of baculovirus expression vector," <i>Bio/Technology</i> , 6:47-55 (January 1988).	

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Sheet **7** of **10****Complete if Known**

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Examiner Name	Joseph T. Weitach
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	GA	MANSOUR, S.L., <i>et al.</i> , "Disruption of the proto-oncogene int-2 in mouse embryo-derived stem cells: a general strategy for targeting mutations to non-selectable genes," <i>Nature</i> , 336(6197):348-352 (November 24, 1988).	
	GB	McCARRICK, J.W. 3rd, <i>et al.</i> , "Positive-negative selection gene targeting with the diphtheria toxin A-chain gene in mouse embryonic stem cells," <i>Transgenic Res.</i> , 2(4):183-190 (July 2, 1993).	
	GC	McCREATH, K.J., <i>et al.</i> , "Production of gene-targeted sheep by nuclear transfer from somatic cells," <i>Nature</i> , 405:1066-1069 (July 29, 2000).	
	GD	McCURRY, K.R., <i>et al.</i> , "Human complement regulatory proteins protect swine-to-primate cardiac xenografts from humoral injury," <i>Nature Med.</i> 1(5):423-427 (May 1995).	
	GE	McKENZIE, I.F., <i>et al.</i> , "Strategies to overcome the anti-Gal alpha (1-3)Gal reaction in xenotransplantation," <i>Transplant Proc.</i> , 28(2):537 (April 1996)	
	GF	MIYAGAWA, S., <i>et al.</i> , "Remodeling of the major pig xenoantigen by N-acetylglucosaminyltransferase III in transgenic pig," <i>J. Biol. Chem.</i> , 276(42):39310-39319 (Oct. 19, 2001).	
	GG	MOREADITH, R.W., <i>et al.</i> , "Gene targeting in embryonic stem cells: the new physiology and metabolism," <i>J. Mol. Med.</i> , 75(3):208-216 (March 1997).	
	GH	MUELLER, S., <i>et al.</i> , "Chimeric pigs following blastocyst injection of transgenic porcine primordial germ cells," <i>Mol. Reprod. Dev.</i> , 54(3):244-254 (November 1999).	
	GI	MULLINS, L.J., <i>et al.</i> , "Transgenesis in the rat and larger mammals," <i>J. Clin. Invest.</i> , 97(7):1557-1560 (April 1, 1996).	
	GJ	NAGASAKA, T., <i>et al.</i> , "Inhibitory effect of $\alpha(1,2)$ fucosyltransferase recombinant adenoviral vector on α Gal expression," <i>Transplantation Proceedings</i> , 30:3837-3838 (1998).	
	GK	ONISHI, A., <i>et al.</i> , "Pig cloning by microinjection of fetal fibroblast nuclei," <i>Science</i> , 289:1188-1190 (August 18, 2000).	
	GL	OSMAN, N., <i>et al.</i> , "Combined transgenic expression of alpha-galactosidase and alpha1,2-fucosyltransferase leads to optimal reduction in the major xenoepitope Galalpha(1,3)Gal," <i>Proc. Natl. Acad. Sci. U S A</i> , 94(26):14677-14682 (December 23, 1997).	
	GM	PERA, M.F., <i>et al.</i> , "Human embryonic stem cells," <i>J. Cell. Sci.</i> , 113 (Pt 1):5-10 (January 2000).	
	GN	PHelps, C.J., <i>et al.</i> , "Production of α 1,3-galactosyltransferase-deficient pigs," <i>Science</i> , 299:411-414 (Jan. 17, 2003).	
	GO	POLEJAEVA, I.A., "Cloning pigs: advances and applications," <i>Reprod.</i> , 58 (Suppl.):293-300 (2001).	
	GP	POLEJAEVA, I.A., <i>et al.</i> , "Cloned pigs produced by nuclear transfer from adult somatic cells," <i>Nature</i> , 407:86-90 (Sept. 7, 2000).	
	GQ	PORTER, A.C.G., <i>et al.</i> , "Gene Targeting: Techniques and applications to transplantation," <i>Transplantation</i> , 64:1227-1235 (Nov. 15, 1997).	

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Sheet **8** of **10****Complete if Known**

Application Number	10/646,970
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First Named Inventor	Carol J. Phelps
Group Art Unit	1632
Examiner Name	Joseph T. Weitach
Attorney Docket Number	10758.105009 REV 1004

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	HA	PRAY, L., "Refining transgenic mice," <i>The Scientist</i> 16(13):34 (June 24, 2002) [http://www.the-scientist.com/yr2002/jun/profile2_020624.html].	
	HB	PURSEL V.G., <i>et al.</i> , "Progress on gene transfer in farm animals," <i>Vet. Immunol. Immunopathol.</i> , 17(1-4):303-312 (December 1987).	
	HC	RAMSOONDAR, J.J., <i>et al.</i> , "Production of α 1,3-galactosyltransferase-knockout cloned pigs expressing human α 1,2-fucosyltransferase," <i>Biol. of Reproduction</i> , 69:437-445 (online before print April 2, 2003).	
	HD	REXROAD, C.E. Jr., <i>et al.</i> , "Production of transgenic sheep with growth-regulating genes," <i>Mol. Reprod. Dev.</i> , 1(3):164-169 (1989).	
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	HF	RUBNITZ, J., <i>et al.</i> , "The minimum amount of homology required for homologous recombination in mammalian cells," <i>Mol. Cell. Biol.</i> , 4(11):2253-2258 (November 1984).	
	HG	SANDRIN, M.S., <i>et al.</i> , "Identification of Gal(α 1,3)Gal as the major epitope for pig-to-human vascularized xenografts," <i>Transplant Rev.</i> , 8(3):134-139 (July 1994).	
	HH	SANDRIN, M.S., <i>et al.</i> , "Characterization of cDNA clones for porcine α (1,3)galactosyl transferase: The enzyme generating the Gal α (1,3)Gal epitope," <i>Xenotransplantation</i> , 1:81-88 (1994).	
	HI	SAO, H., <i>et al.</i> , "A new marrow T cell depletion method using anti-CD6 monoclonal antibody-conjugated magnetic beads and its clinical application for prevention of acute graft-vs.-host disease in allogeneic bone marrow transplantation: Results of a phase I-II trial," <i>Intl. J. Hematol.</i> , 69(1):27-35 (January 1999).	
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	HL	SHARMA, A., <i>et al.</i> , "Pig cells that lack the gene for α 1,3-galactosyltransferase express low levels of the gal antigen," <i>Transplantation</i> , 75(4):430-436 (Feb. 7, 2003).	
	HM	SIMONS, J.P., <i>et al.</i> , "Gene transfer into sheep," <i>Bio/Technology</i> , 6(1):179-183 (January 1988).	
	HN	SMITH, C.M., "Technical knockout: Gene-targeting strategies provide an avenue for studying gene function," <i>The Scientist</i> , 14(15):32 (July 24, 2000) www.the-scientist.com/yr2000/jul/profile_000724.html	
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	HP	STARZL, T.E., <i>et al.</i> , "The biological basis of and strategies for clinical xenotransplantation," <i>Immunol. Rev.</i> , 141:213-244 (October 1994).	

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	IA	STARZL, T.E., <i>et al.</i> , "Will xenotransplantation ever be feasible?" <i>J. Am. Coll. Surg.</i> , 186(4):383-387 (April 1998).	
	IB	STOLBERG, S.G., "Could this pig save your life?" <i>N. Y. Times Magazine.</i> , October 3, 1999, pp. 46-51.	
	IC	STONE, K.R., <i>et al.</i> , "Porcine and bovine cartilage transplants in cynomolgus monkey," <i>Transplantation</i> , 63(5):640-645 (March 15, 1997).	
	ID	STRAHAN, K., <i>et al.</i> , "Pig alpha 1,3galactosyltransferase: A major target for genetic manipulation in xenotransplantation," <i>Frontiers in Bioscience</i> , 1:e34-41 (July 1, 1996) [www.bioscience.org/1996/v1/e/strahan1/htmls/34-41.htm].	
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	IK	TEARLE, R.G., <i>et al.</i> , "The alpha-1,3-galactosyltransferase knockout mouse," <i>Transplantation</i> , 61(1):13-19 (Jan. 15, 1996).	
	IL	THALL, A.D., <i>et al.</i> , "Oocyte galalpha1,3gal epitopes implicated in sperm adhesion to the zona pellucida glycoprotein ZP3 are not required for fertilization in the mouse," <i>J. Biol. Chem.</i> , 270(27):21437-21440 (Sept. 15, 1995).	
	IM	THOMAS, K.R., <i>et al.</i> , "Site-directed mutagenesis by gene targeting in mouse embryo-derived stem cells," <i>Cell</i> , 51(3):503-512 (November 6, 1987).	
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	JA	VANHOVE, B., <i>et al.</i> , "Transcriptional and posttranscriptional regulation of α 1,3-galactosyltransferase in activated endothelial cells results in decreased expression of Gal α 1,3Gal," <i>Glycobiology</i> , 8(5):481-487 (May 1998).	
	JB	VANHOVE, B., <i>et al.</i> , "Variability of alpha 1,3-galactosyltransferase splicing isoforms in pig tissues," <i>Transplant Proc.</i> 28(2):622-623 (April 1996).	
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	JD	VIZE, P.D., <i>et al.</i> , "Introduction of a porcine growth hormone fusion gene into transgenic pigs promotes growth," <i>J. Cell Sci.</i> , 90 (Pt 2):295-300 (June 1988).	
	JE	WAGNER, "Development of transgenic pigs," <i>J. Cellular Biochem.</i> , 13B (Suppl.):164 (1989) (Abstract).	
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	JI	YE, Y., <i>et al.</i> , "Evidence that intravenously administered a-galactosyl carbohydrates reduce baboon serum cytotoxicity to pig kidney cells (PK15) and transplanted pig hearts," <i>Transplantation</i> , 58(3):330-337 (Aug. 15, 1994).	
	JJ	YAREMA, K. <i>et al.</i> , "Characterizing glycosylation pathways," <i>Genome Biology</i> , 2(5):1-10 (May 1, 2001)	
	JK	CASTAGLIUOLO, I. <i>et al.</i> , "Clostridium difficile toxin a carboxyl-terminus peptide lacking ADP-ribosyltransferase activity acts as a mucosal adjuvant," <i>Infection and Immunity</i> , 72(5):2827-2836, (May 2004)	

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